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OT06 Rec'd PCT/PTO

29 AUG 2002

Patent  
Attorney's Docket No. 033136-269

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

DAVID ELSLEY

Application No.: 10/089,362

Filed: March 25, 2002

For: COMBINED THERAPIES FOR  
TREATING ATHEROSCLEROSIS IN  
MAMMALS

Group Art Unit: Unassigned

Examiner: Unassigned

Confirmation No.: Unassigned

INFORMATION DISCLOSURE STATEMENT  
TRANSMITTAL LETTER

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- ☒ No additional fee for submission of an IDS is required.
- ☐ The fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ A certification under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ A certification under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- ☐ Charge \$\_\_\_\_\_ to Deposit Account No. 02-4800 for the fee due.
- ☐ A check in the amount of \$\_\_\_\_\_ is enclosed for the fee due.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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By: Lorna L. Tanner  
Lorna L. Tanner  
Registration No. 50,782

Date: August 28, 2002



Patent  
Attorney's Docket No. 033136-269

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

|                             |   |                            |
|-----------------------------|---|----------------------------|
| In re Patent Application of | ) |                            |
|                             | ) |                            |
| DAVID ELSLEY                | ) | Group Art Unit: Unassigned |
|                             | ) |                            |
| Application No.: 10/089,362 | ) | Examiner: Unassigned       |
|                             | ) |                            |
| Filed: March 25, 2002       | ) | Confirmation No.: Unknown  |
|                             | ) |                            |
| For: COMBINED THERAPIES FOR | ) |                            |
| TREATING ATHEROSCLEROSIS IN | ) |                            |
| MAMMALS                     | ) |                            |
|                             | ) |                            |

**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed.

**Foreign Patents**

1. CA 2,296,723, published March 11, 1999 (front page with English abstract only).
2. International Publication No. WO 96/34613, published November 7, 1996.
3. International Publication No. WO 98/07436, published February 26, 1998.
4. International Publication No. WO 99/11260, published March 11, 1999.
5. International Publication No. WO 99/13890, published March 25, 1999.
6. International Publication No. WO 00/29003, published May 25, 2000.

**Other Publications**

7. Alegret, M., et al. "Effect of hypolipidemic drugs on key enzyme activities related to lipid metabolism in normolipidemic rabbits." *E. J. Pharmacol.* 347: 283-291 (1998).
8. Bando, T., et al. "Fluvastatin Suppresses Atherosclerotic Progression, Mediated Through Its Inhibitory Effect on Endothelial Dysfunction, Lipid Peroxidation, and Macrophage Deposition." *J. Cardio. Pharmacol.* 35: 134-144 (2000).

9. Bocan, T.M.A., et al. "Antiatherosclerotic activity of inhibitors of 3-hydroxy-3-methylglutaryl coenzyme A reductase in cholesterol-fed rabbits: a biochemical and morphological evaluation." *Atherosclerosis*. 111: 127-142 (1994).
10. Dowell, F.J., et al. "Development and Progression of Atherosclerosis in Aorta From Heterozygous and Homozygous WHHL Rabbits." *Arteriosclerosis, Thrombosis, and Vascular Biology*. 15(8): 1152-1160 (1995).
11. Gambhir, D.S. "Statin Therapy for Prevention of Coronary Artery Disease with Average Cholesterol Levels." *Indian Heart J.* 51: 19-21 (1999).
12. Farnier, M., et al. "Current and Future Treatment of Hyperlipidemia: The Role of Statins." *Am. J. Cardiol.* 82(48): 3J-10J (1998).
13. Kroon, A.A., et al. "The effect of cholesterol reduction on the endothelial function and progression of atherosclerosis in WHHL rabbits." *Atherosclerosis*. 103(221-230 (1993).
14. LaRosa, J.C. "Future Cardiovascular End Point Studies: Where Will the Research Take Us?" *Am. J. Cardiol.* 84: 454-458 (1999).
15. Pederssen, T.R. "Statin trials and goals of cholesterol-lowering therapy after AMI." *Am. Heart J.* 138: S177-S182 (1999).
16. Reynolds, J.E.F. "Martindale, the Extra Pharmacopeia, Thirty-second Edition." London, Royal Pharmaceutical Society. p. 1268-1279.
17. Ross, S.D., et al. "Clinical Outcomes in Statin Treatment Trials." *Arch. Intern. Med.* 159: 1973-1802 (1999).
18. Vaughan, C.J., et al. "Neuroprotective Properties of Statins in Cerebral Ischemia and Stroke." *Stroke*. 30: 1969-1973 (1999).
19. Wheeler, D.C. "Are There Potential Non-Lipid-Lowering Uses of Statins?" *Drugs*. 5(6): 517-522 (1998).

The documents are being submitted within 3 months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later, therefore no fee or statement is required under 37 C.F.R. § 1.97(b).

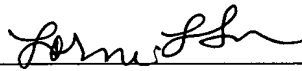
By citing the above references, Applicants do not acquiesce or admit that any of these documents are "prior art" under 35 U.S.C. Applicants specifically reserve the right, where

appropriate, to antedate any of the cited documents by an appropriate showing under 37 C.F.R. §1.131, §1.604, §1.608 or any other suitable means.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

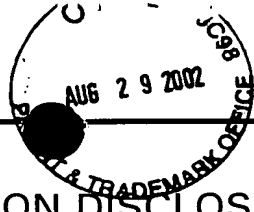
Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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Date: August 28, 2002



Substitute for form 1449A/PTO

ATTORNEY'S DKT  
033136-269APPLICATION No.  
10/089,362INFORMATION DISCLOSURE  
STATEMENT BY APPLICANTAPPLICANT  
DAVID ELSLEYFILING DATE  
March 25, 2002GROUP  
Unassigned

## U.S. PATENT DOCUMENTS

| Examiner<br>Initials | U.S. Patent Document |                         | Name of Patentee or Applicant<br>of Cited Document | Date of Publication<br>(MM-DD-YYYY) |
|----------------------|----------------------|-------------------------|--|-------------------------------------|
|                      | Number               | Kind Code<br>(if known) |  |                                     |
|                      |                      |                         |  |                                     |
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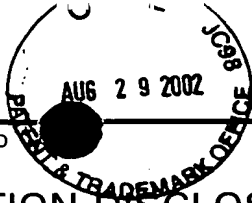
## FOREIGN PATENT DOCUMENTS

| Examiner<br>Initials | Foreign Patent Document |                         | Country                | Date of Publication<br>(MM-DD-YYYY) | Translation |    |
|----------------------|-------------------------|-------------------------|------------------------|-------------------------------------|-------------|----|
|                      | Number                  | Kind Code<br>(if known) |                        |                                     | Yes         | no |
|                      | 2,296,723               |                         | Canada (abstract only) | 03-11-1999                          |             |    |
|                      | 96/34613                |                         | WIPO                   | 11-07-1996                          |             |    |
|                      | 98/07436                |                         | WIPO                   | 02-26-1998                          |             |    |
|                      | 99/11260                |                         | WIPO                   | 03-11-1999                          |             |    |
|                      | 99/13890                |                         | WIPO                   | 03-25-1999                          |             |    |
|                      | 00/29003                |                         | WIPO                   | 05-25-2000                          |             |    |
|                      |                         |                         |                        |                                     |             |    |

## NON PATENT LITERATURE DOCUMENTS

| Examiner<br>Initials | Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |
|----------------------|---|
|                      | ALEGRET, M., et al. "Effect of hypolipidemic drugs on key enzyme activities related to lipid metabolism in normolipidemic rabbits." <i>E. J. Pharmacol.</i> 347: 283-291 (1998).  |
|                      | BANDOH, T., et al. "Fluvastatin Suppresses Atherosclerotic Progression, Mediated Through Its Inhibitory Effect on Endothelial Dysfunction, Lipid Peroxidation, and Macrophage Deposition." <i>J. Cardio. Pharmacol.</i> 35: 134-144 (2000).                 |
|                      | BOCAN, T.M.A., et al. "Antiatherosclerotic activity of inhibitors of 3-hydroxy-3-methylglutaryl coenzyme A reductase in cholesterol-fed rabbits: a biochemical and morphological evaluation." <i>Atherosclerosis.</i> 111: 127-142 (1994).                  |
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|                      | GAMBHIR, D.S. "Statin Therapy for Prevention of Coronary Artery Disease with Average Cholesterol Levels." <i>Indian Heart J.</i> 51: 19-21 (1999).  |
|                      | FARNIER, M., et al. "Current and Future Treatment of Hyperlipidemia: The Role of Statins." <i>Am. J. Cardiol.</i> 82(48): 3J-10J (1998).  |
|                      | KROON, A.A., et al. "The effect of cholesterol reduction on the endothelial function and progression of atherosclerosis in WHHL rabbits." <i>Atherosclerosis.</i> 103(221-230 (1993).   |
|                      | LAROSA, J.C. "Future Cardiovascular End Point Studies: Where Will the Research Take Us?" <i>Am. J. Cardiol.</i> 84: 454-458 (1999).   |

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.



|   |                               |                               |
|---|-------------------------------|-------------------------------|
| Substitute for form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b> | ATTORNEY'S DKT<br>033136-269  | APPLICATION No.<br>10/089,362 |
|   | APPLICANT<br>DAVID ELSLEY     |                               |
|   | FILING DATE<br>March 25, 2002 | GROUP<br>Unassigned           |
|   |                               |                               |

|                       |   |                    |  |
|-----------------------|---|--------------------|--|
|                       | PEDERSSSEN, T.R. "Statin trials and goals of cholesterol-lowering therapy after AMI." <i>Am. Heart J.</i> 138: S177-S182 (1999).    |                    |  |
|                       | REYNOLDS, J.E.F. "Martindale, the Extra Pharmacopeia, Thirty-second Edition." London, Royal Pharmaceutical Society. p. 1268-1279.   |                    |  |
|                       | ROSS, S.D., et al. "Clinical Outcomes in Statin Treatment Trials." <i>Arch. Intern. Med.</i> 159: 1973-1802 (1999).                 |                    |  |
|                       | VAUGHAN, C.J., et al. "Neuroprotective Properties of Statins in Cerebral Ischemia and Stroke." <i>Stroke.</i> 30: 1969-1973 (1999). |                    |  |
|                       | WHEELER, D.C. "Are There Potential Non-Lipid-Lowering Uses of Statins?" <i>Drugs.</i> 5(6): 517-522 (1998).                         |                    |  |
|                       |   |                    |  |
|                       |   |                    |  |
| Examiner<br>Signature |   | Date<br>Considered |  |

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